Final Amendments to 247 CMR 2.00, 6.00 and 10.00

Blue text = amendments per the Emergency Regulations as promulgated November 1, 2012
Red text = amendments following public hearing as made final and put in effect on February 1, 2013

2.00: Definitions

Additional definitions pertaining to:

(1) nuclear pharmacies are contained in 247 CMR 13.00;

(2) disciplinary proceedings are contained in 247 CMR 10.00;

(3) continuous quality improvement programs are contained in 247 CMR 15.00; **and**

(4) duty to report certain factors of pharmacy operations are contained in 247 CMR 6.15.

6.01 Application for Registration to Manage and Operate a Pharmacy or a Pharmacy Department; Inspection of a Proposed Pharmacy or Pharmacy Department

...

(5) The Board may require an inspection of the pharmacy or pharmacy department before final approval of the application is granted. All proposed pharmacies and pharmacy departments shall comply with the following requirements:

...

(c) Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) or performs sterile compounding shall, in addition to the 300 square feet required by 247 CMR 6.01(5)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. **The pharmacy shall obtain approval from the Board indicating compliance** with 247 CMR 6.01~~(5)(b)~~ and United States Pharmacopeia General Chapter 797 prior **to initial operation of central intravenous admixture services. The Board's approval shall be conspicuously posted ~~conspicuously,~~ and visible to the public, on the pharmacy premises.** This clean room shall meet the following requirements:

6.15: Duty to Report Certain Factors of Pharmacy Operations

(1) Definitions:

(a) Abnormal Results means results of viable and nonviable testing, such as for environmental contaminants and potency, that are not within acceptable United States Pharmacopeia General Chapter 797 standards or criteria.

(~~a~~b) Accreditation means a process by which a professional association or

non-governmental agency grants recognition to a pharmacy for demonstrated ability to meet certain pre-defined criteria.

(~~b~~c) Disciplinary actions means actions including, but not limited to revocation, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.

(~~e~~d) Federal agency means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.

(~~d~~e) State agency means any U.S. State or Territory that licenses or otherwise regulates pharmacies or pharmacist practice.

(~~e~~f) Sterile compounding means the preparation, mixing, assembling, packaging, and labeling of a drug or device that is required to be prepared in accordance with United States Pharmacopeia General Chapter ~~standard~~ **797 and** dispensed **pursuant to a valid prescription as defined by** ~~M.G.L. c. 94C.~~ 247 CMR 2.00.

(2) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board within 7 business days of receipt, in a manner and format determined by the Board, all non-routine notices, correspondence, and disciplinary actions as defined herein.

(3) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall report to the Board any adverse change in status of accreditation, including but not limited to withdrawal, discontinuance, termination, revocation, suspension, probation, or warning. All such reports shall be made within 7 business days of an action taken by the accrediting agency, and in a manner determined by the Board.

(4) Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, and pharmacist licensed or registered pursuant to M.G.L. c. 112, § 24, shall provide the Board with responsive documents sent from a registrant or licensee to a state or federal agency with respect to reports or responses submitted pursuant to 247 CMR 6.15 (2) and (3). All such materials shall be provided to the board

within seven business days of response to the aforementioned state or federal agency.

(5) **Every pharmacy licensed pursuant to M.G.L. c. 112, § 39, that performs central intravenous admixture services (CIVAS), or engages in sterile compounding, shall report to the Board every six months, or upon request by the Board, at a minimum, the following information:**

(a) **total number** and type **of prescriptions dispensed, distribution data identifying the states in which the prescriptions were distributed, status of any non-resident licenses issued by other states, hood certifications required by 247 CMR 6.01(5)(c) 5,** and all International Organization for Standardization (ISO) certifications in the pharmacy, **status of CIVAS approval(s) where applicable, and any other information required by the Board.**

(b) **All such reports shall be accurate and comply with the Board's reporting requirements.**

(c) **All reports shall be accompanied by an affidavit attesting compliance with all laws and regulations pertinent to sterile compounding** and United States Pharmacopeia General Chapter 797**. This attestation shall be made under pains and penalties of perjury, and include attestation to the following "this registrant/licensee only** ~~prepares and~~ **dispenses medication pursuant to a valid prescription as defined in M.G.L. c. 94C for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient."**

(6) **Every pharmacy** engaged in sterile compounding and **licensed pursuant to M.G.L. c. 112, § 39 shall report within 7 business days** of identification ~~adverse events relating to preparation of medications in that pharmacy.~~ errors relating to the preparation of medications in that pharmacy inconsistent with United States Pharmacopeia General Chapter 797 standards or criteria for factors including but not limited to pyrogenicity, stability, improper composition, mislabeling, or sterility.

(7) **Every pharmacy licensed pursuant to M.G.L. c. 112, § 39 shall report within 7 business days all abnormal results, including failure of certification as required pursuant to 247 CMR 6.01(5)(c), and identification of environmental contaminants** or improper potency **in that pharmacy** ~~as required pursuant to 247 CMR 9.01: *Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments*(3).~~ inconsistent with United States Pharmacopeia General Chapter 797 standards or criteria.

(8) **Failure to comply with reporting requirements described in 247 CMR 6.15 (2) – (7) or to cooperate fully in the Board's investigation of any such report**

to the Board shall be grounds for disciplinary action pursuant to 247 CMR 10.03(1)(q).

10.02: Definitions

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Conviction shall include any guilty verdict or finding of guilt and any admission to or finding of sufficient facts to warrant a finding of guilt, regardless of adjudication, a continuance without a finding, and any plea of guilty or *nolo contendere*, of or to a crime in any jurisdiction, which has been accepted by the court, whether or not a sentence has been imposed. A conviction of any person licensed or registered by the Board shall be conclusive evidence of the commission of that crime in any disciplinary proceeding against such person based upon the conviction.

10.03: Grounds for Discipline

(1) The Board may impose disciplinary action against an individual or entity licensed or registered by the Board, on one or more of the grounds for discipline listed in M.G.L. c. 112, § 61 or one or more of the following grounds:

...

(w) Failing to comply with recognized ethical standards of the profession, including, but not limited to, the standards of practice of pharmacists, pharmacy interns, pharmacies and pharmacy departments set forth in 247 CMR 9.01: *Code of Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments*; ~~and~~

(x) Violation of M.G.L. c. 94C or any rules or regulations promulgated thereunder~~.~~ ; (striking the period and replacing with the semicolon)

(y) Failing to report or failing to accurately report to the Board ~~in writing,~~ **within** seven business days, in a manner and format determined by the Board, discipline ~~30 days, any disciplinary action~~ **(247 CMR 10.06)** ~~taken against a registrant or licensee by an entity or its agent, including but not limited to, a governmental authority, a health care facility, an employer, or a professional pharmacy related society (international, national, state or local),~~ **on the basis of actions listed in 247 CMR 10.03 (1);**

(z) Failing to report to the Board, in a manner and format determined by the Board, within seven business ~~writing, within 30~~ **days, any final action (including license surrender or resignation) regarding a registrant or licensee, including any against any other health care related professional registration or license held by a registrant or licensee, by any other governmental authority in this state or another jurisdiction;**

(aa) Failing to report to the Board, in writing, within 30 days, any pending criminal charge or conviction, as defined in 247 CMR 10.02, of a registrant or licensee, in Massachusetts or any other jurisdiction; and

(bb) Failure to comply with reporting requirements described in 247 CMR 6.15 (2) – (7) or to cooperate fully in the Board's investigation of any such report.

10.06: Disciplinary Action

Actions which may be taken by the Board ~~**after investigation of a complaint**~~ are:

…

(8) Summary Cease and Desist Notice. A summary cease and desist notice may be imposed by the Board or Board President prior to hearing in order to stop or restrict operations by a registrant or licensee to immediately protect the public health, safety or welfare. The Board or Board President may rescind or amend a summary cease and desist notice.

(9) Summary Quarantine Notice. A summary quarantine notice may be imposed by the Board or Board President prior to hearing in order to prevent the use of medications prepared by or in possession of a registrant or licensee to immediately protect the public health, safety or welfare. The Board or Board President may rescind or amend a summary cease and desist notice.

10.08: Summary Cease and Desist and Quarantine Notice

(1) If, based upon affidavits or other evidence, the Board or Board President determines that a registrant or licensee or the products prepared by a registrant or licensee are an immediate or serious threat to the public health, safety, or welfare, the Board or Board President may:

(a) issue a Cease and Desist Notice and/or Quarantine Notice, requiring non-disciplinary **cessation or restriction of any and all pharmacy** ~~**Operations**~~ operations**, and prohibiting the use of medications prepared by or in possession of a pharmacy**; ~~**and**~~ or

(b) issue a Cease and Desist Notice placing non-disciplinary restrictions on a Board registrant or licensee, to the extent necessary to avert a continued threat, pending final investigation results.

(2) Requirements of the Cease and Desist ~~**Order**~~ Notice **and/or Quarantine Notice shall remain in effect until the Board** or Board President **rescinds** or amends

such requirements or until such time as the Board takes final action on any related pending complaint and the Board issues a final decision.

(3) **A hearing limited to the determination of the necessity of Notices issued pursuant to** 247 CMR 10.06(8), 248 CMR 10.06(9), or **247 CMR 10.08 (1) shall be afforded the registrant or licensee within** 15 business ~~21~~ **days of the Board or Board President's action.**